

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

F_R2

C Number: C20007

Lock Date: 03/27/2007

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

TDMSE Version: 2.1.0

Note: Animals arranged according to days on test.

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ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor
+ .. Tissue examined microscopically
x .. Lesion present
| .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

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**males
(cont...)**

CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

- * .. Total animals with tissue examined microscopically; Total animals with tumor
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**males
(cont...)**

+

Interstitial Cell Adenoma X X X X X

Bilateral, Interstitial Cell, Adenoma
Interstitial Cell, Adenoma

HEMATOPOIETIC SYSTEM

Lymph Node +

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- ✗ Lesion present

.. Lesion present

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- + .. Tissue examined
- x Lesion present

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.. Lesion present
 Insufficient tissue

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Lab: BAT

Acinus, Adenoma 1

.....

.....

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CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

Carcinoma X 1

Fibrous Histiocytoma, Metastatic,
Skeletal Muscle 1

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x .. Lesion present

x .. Eosin present
| .. Insufficient tissue

M .. Missing tissue

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Lab: BAT

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Carcinoma						X																	1
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Bilateral, Interstitial Cell, Adenoma	X	X	X	X	X	X	X	X															29
Interstitial Cell, Adenoma																	X					X	8

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

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A .. Autolysis precludes evaluation

- + .. Tissue examined
- x Lesion present

BLANK Not examined microscopically

x .. Lesion present
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Peripheral Nerve 2

Spinal Cord

Glioma Malignant 1

RESPIRATORY SYSTEM

Alveolar/Bronchiolar Adenoma X 1

Alveolar/Bronchiolar Adenoma, Multiple X 1

Alveolar/Bronchiolar Carcinoma X

Fibrous Histiocytoma, Metastatic,
Skeletal Muscle 1

Mediastinum, Osteosarcoma, Metastatic,
Bone 1

SPECIAL SENSES SYSTEM

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URINARY SYSTEM

Urinary System

Urethra

SYSTEMIC LESIONS

Leukemia Mononuclear X X 7

Lymphoma Malignant 1

Mesothelioma Malignant X X 3

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**males
(cont...)**

CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

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CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x .. Lesion present

.. Lesion present
 .. Insufficient tissue

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Lab: BAT

GENERAL BODY SYSTEM

Tissue NOS
Rhabdomyosarcoma

GENITAL SYSTEM

Coagulating Gland + +

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+ Tissue examined microscopically

x Lesion present

.. Lesion present
 Insufficient tissue

M .. Missing tissue

A Autolysis precludes evaluation

BLANK Not examined microscopically

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Lab: BAT

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Fibrous Histiocytoma, Metastatic, Skin																					1
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Carcinoma																					1
Schwannoma Malignant																					1
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Adenoma																				X	1
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Bilateral, Interstitial Cell, Adenoma	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	32
Interstitial Cell, Adenoma				X	X														X	X	12

HEMATOPOIETIC SYSTEM

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M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

x .. Lesion present

BLANK .. Not examined microscopically

x .. Lesion present
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Mast Cell Tumor Malignant

Mast Cell Tumor Malignant

INTEGUMENTARY SYSTEM

Fibroadenoma 1

Subcutaneous Tissue, Fibroma X X X 5

Subcutaneous Tissue, Fibrous

Histiocytoma

MUSCULOSKELETAL SYSTEM

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X .. Lesion present
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NERVOUS SYSTEM

RESPIRATORY SYSTEM

SPECIAL SENSES SYSTEM

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Lab: BAT

URINARY SYSTEM

SYSTEMIC LESIONS

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x .. Lesion present
I .. Insufficient tissue

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CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

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CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

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Lab: BAT

GENERAL BODY SYSTEM

Peritoneum	1
Paraganglioma	1

GENITAL SYSTEM

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M Missing tissue

† Tissue examined microscopically

A Autolysis precludes evaluation

- + .. Tissue examined
- x Lesion present

x .. Lesion present
| Insufficient tissue

BLANK Not examined microscopically.

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HEMATOPOIETIC SYSTEM

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A.. Autolysis precludes evaluation

x Lesion present

BLANK Not examined microscopically

.. Lesion present
 Insufficient tissue

BEANK .. Not examined microscopically

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Lab: BAT

INTEGUMENTARY SYSTEM

MUSCULOSKELETAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

† ... Tissue examined microscopically

x Lesion present

.. Lesion present
 Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

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Lab: BAT

NERVOUS SYSTEM

RESPIRATORY SYSTEM

SPECIAL SENSES SYSTEM

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URINARY SYSTEM

SYSTEMIC LESIONS

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	4	4	4	5	5	5	5	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7	7	7	7	
	0	3	4	4	5	5	2	5	5	8	2	4	6	7	7	7	7	8	9	0	2	2	2	2	2	2	2	
	3	0	7	1	4	8	6	9	9	9	0	5	0	3	3	9	9	4	9	7	7	7	7	7	7	7	7	
<hr/>																												
FISCHER 344 RATS MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1.0 G/KG	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	9	7	6	8	8	8	5	9	5	5	6	6	8	6	8	7	8	6	5	5	5	5	6	6	6	7		
	3	3	0	8	6	3	3	9	4	7	3	8	5	1	4	1	2	7	9	1	2	8	6	9	0			

ALIMENTARY SYSTEM

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SYSTEMIC LESIONS

Multiple Organ

Leukemia Mononuclear

Lymphoma Malignant

Mesothelioma Malignant

X

x

**males
(cont...)**

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.. Lesion present
 Insufficient tissue

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- + .. Tissue examined microscopically
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Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
.....																							
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Sarcoma																							1
.....																							
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
.....																							
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
.....																							
Tooth					+	+					+	+	+			+							11

CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: Gavage

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	7	7	7	7	7	7	8	8	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9
FISCHER 344 RATS MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1.0 G/KG	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	
	7	7	7	8	8	9	5	6	7	7	8	8	9	9	5	6	6	6	7	7	9	9	9	9	9	9	9	9	9	0	
	2	4	8	0	9	5	5	2	5	9	1	7	4	6	6	4	5	6	7	0	1	2	7	8	0	* TOTALS					

Pheochromocytoma Benign X 2

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Epididymis

Preputial Gland Adenoma

Prostate

5

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x .. Lesion present

.. Lesion present
 Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK - Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

HEMATOPOIETIC SYSTEM

* Total animals with tissue examined microscopically; Total animals with tumor

M Missing tissue

+ Tissue examined microscopically

A Autolysis precludes evaluation

- + .. Tissue examined
- x Lesion present

BLANK Not examined microscopically

.. Lesion present
 Insufficient tissue

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: Gavage

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

Skeletal Muscle

INTEGUMENTARY SYSTEM

MUSCULOSKELETAL SYSTEM

NERVOUS SYSTEM

* ... Total animals with tissue examined microscopically; Total animals with tumor

† ... Tissue examined microscopically

x ... Lesion present

x .. Lesion present
| Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK - Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

RESPIRATORY SYSTEM

SPECIAL SENSES SYSTEM

URINARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x .. Lesion present

.. Lesion present
 .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

SYSTEMIC LESIONS

Multiple Organ	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Leukemia Mononuclear												X	X									X	X	X	11
Lymphoma Malignant																									1
Mesothelioma Malignant																					X		X		3

*** END OF MALE DATA ***

* .. Total animals with tissue examined microscopically; Total animals with tumor
+ .. Tissue examined microscopically
x .. Lesion present
| .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

CAS Number: 9000-38-5

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

† .. Tissue examined microscopically

A .. Autolysis precludes evaluation

- ✗ Lesion present

BLANK Not examined microscopically

x .. Lesion present
| Insufficient tissue

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

Sarcoma, Metastatic, Stomach Glandular

Stomach, Glandular Sarcoma

Tooth

CARDIOVASCULAR SYSTEM

Blood Vessel

Heart

Fibrosarcoma, Metastatic, Lung

ENDOCRINE SYSTEM

Adrenal Cortex

Adrenal Medulla

Pheochromocytoma Benign

Islets, Pancreas

Adenoma

* .. Total animals with tissue examined microscopically; Total animals with tumor

† .. Tissue examined microscopically

- ✗ Lesion present

.. Lesion present
 Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

x .. Lesion present

BLANK .. Not examined microscopically

X .. Essien present
| .. Insufficient tissue

DEAN :: Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

HEMATOPOIETIC SYSTEM

INTEGUMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

x .. Lesion present

BLANK .. Not examined microscopically

X .. Essien present
| .. Insufficient tissue

BEAK: Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

MUSCULOSKELETAL SYSTEM

NERVOUS SYSTEM

RESPIRATORY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: Gavage

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

SPECIAL SENSES SYSTEM

URINARY SYSTEM

SYSTEMIC LESIONS

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x .. Lesion present

| .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A.. Autolysis precludes evaluation

x .. Lesion present

BLANK - Not examined microscopically

Insufficient tissue

BEANK :: Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: Gavage

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

HEMATOPOIETIC SYSTEM

INTEGUMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

x .. Lesion present

BLANK .. Not examined microscopically

X .. Essien present
| .. Insufficient tissue

BEANK :: Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: Gavage

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

Fibroadenoma, Multiple

X X X

Skin

MUSCULOSKELETAL SYSTEM

Bone

NERVOUS SYSTEM

Brain

RESPIRATORY SYSTEM

Lung

Carcinoma, Metastatic, Mammary Gland

Pheochromocytoma Malignant,
Metastatic, Adrenal Medulla

Nose

Trachea

* .. Total animals with tissue examined microscopically; Total animals with tumor
+ .. Tissue examined microscopically
x .. Lesion present
! .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla															X									1
Mesentery															+									9
Oral Mucosa																					+			1
Squamous Cell Papilloma																					X			1

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A. Autolysis precludes evaluation

x .. Lesion present

BLANK - Not examined microscopically

| Insufficient tissue

BEANK :: Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

CARDIOVASCULAR SYSTEM

ENDOCRINE SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

x ... Lesion present

BLANK - Not examined microscopically

.. Lesion present
 Insufficient tissue

BEANK .. Not examined microscopically

TDMS No. 20007 - 05

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

HEMATOPOIETIC SYSTEM

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Adenoma													X										1
Carcinoma											X		X										3
Fibroadenoma				X	X	X		X		X		X	X	X	X	X						X	17

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

x .. Lesion present

BLANK .. Not examined microscopically

X .. Essien present
| .. Insufficient tissue

BEAN :: Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

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Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

SPECIAL SENSES SYSTEM

URINARY SYSTEM

SYSTEMIC LESIONS

Multiple Organ
Leukemia Mononuclear

* .. Total animals with tissue examined microscopically; Total animals with tumor
+ .. Tissue examined microscopically
x .. Lesion present
| .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

TDMS No. 20007 - 05

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A.. Autolysis precludes evaluation

x ... Lesion present

BLANK .. Not examined microscopically

x .. Lesion present
| Insufficient tissue

BEANK :: Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: Gavage

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

Multiple Organ

Leukemia Mononuclear

females (cont...)

- * .. Total animals with tissue examined microscopically; Total animals with tumor
- + .. Tissue examined microscopically
- x .. Lesion present
- | .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

† ... Tissue examined microscopically

A .. Autolysis precludes evaluation

Lesion present

BLANK Not examined microscopically

x .. Lesion present
| Insufficient tissue

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

* Total animals with tissue examined microscopically; Total animals with tumor

† Tissue examined microscopically

x Lesion present

| Insufficient tissue

M Missing tissue

A Autolysis precludes evaluation

BLANK Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

HEMATOPOIETIC SYSTEM

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Carcinoma									X												1
Fibroadenoma	X		X		X		X								X	X		X			13
Fibroadenoma, Multiple										X							X				2

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

x .. Lesion present

ANK .. Not examined microscopically

X .. Essien present
| .. Insufficient tissue

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

MUSCULOSKELETAL SYSTEM

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Osteoma																					1
Osteosarcoma																	X				1
Osteosarcoma, Metastatic, Skin																					1
Skeletal Muscle															+						1
Rhabdomyosarcoma															X						1

NERVOUS SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

† ... Tissue examined microscopically

- + .. Tissue examined
- x Lesion present

.. Lesion present
 Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

RESPIRATORY SYSTEM

SPECIAL SENSES SYSTEM

URINARY SYSTEM

SYSTEMIC LESIONS

* .. Total animals with tissue examined microscopically; Total animals with tumor
+ .. Tissue examined microscopically
x .. Lesion present
| .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: Gavage

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

Multiple Organ

Leukemia Mononuclear

- * .. Total animals with tissue examined microscopically; Total animals with tumor
- + .. Tissue examined microscopically
- x .. Lesion present
- | .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

† ... Tissue examined microscopically

x Lesion present

.. Lesion present
 Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

A .. Autolysis precludes evaluation
I ANK Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

ALIMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

x .. Lesion present

BLANK .. Not examined microscopically

X .. Essien present
| .. Insufficient tissue

DEAN :: Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x .. Lesion present

| Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK - Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

Time Report Requested: 08:01:35

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

HEMATOPOIETIC SYSTEM

INTEGUMENTARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

† ... Tissue examined microscopically

A.. Autolysis precludes evaluation

x Lesion present

BLANK Not examined microscopically

x .. Lesion present
| Insufficient tissue

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/M

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

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Lab: BAT

MUSCULOSKELETAL SYSTEM

NERVOUS SYSTEM

RESPIRATORY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x ... Lesion present

x .. Lesion present
| Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK - Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kaya kaya extract

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Lab: BAT

SPECIAL SENSES SYSTEM

Ear	+	1
Neural Crest Tumor	X	1
Eye	+	50
Harderian Gland	+	50
Zymbal's Gland	+	1
Adenoma	X	1

URINARY SYSTEM

SYSTEMIC LESIONS

* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

x ... Lesion present

| Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK - Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: Gavage

Species/Strain: RATS/F 344/N

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 02/20/2009

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Lab: BAT

*** END OF REPORT ***

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+ .. Tissue examined microscopically
x .. Lesion present
| .. Insufficient tissue

M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically